| DRUG UTILIZATION REVIEW BOARD<br>Meeting Minutes, Open Session<br>March 8, 2006 | | |
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| **DRUG UTILIZATION REVIEW BOARD**<br>Meeting Minutes, Open Session<br>EDS/White Lakes Mall<br>Wichita/Kansas City Room<br>Topeka, Kansas<br>March 8, 2006 | **Members Present:** R. Kevin Bryant, M.D.,C.M.D; Michael Burke, M.D.,Ph.D.; Brenda Schewe, M.D., Kevin Waite, PharmD; Tom Wilcox, R.Ph.; Kevin Kentfield, PharmD; Dennis Grauer, Ph.D.; Linda Kroeger, ARNP; Roger Unruh, D.O.<br>**DHPF Staff Present:** Anne Ferguson R.Ph.; Mary Lesperance, R.Ph.; Wanda Pohl<br>**EDS Staff Present:** Karen Kluczykowki, R.Ph.; Debra Quintanilla, R.N. | **Representatives:** Jason Crowe PharmD (ACS Heritage); Wayne Moore, M.D. (Children's Mercy Hospital); David Case (Astellas Pharma); Paul Fung (FirstGuard Health Plan); Peter Dow (Alphama); Jason Beal, (BMS) Stephanie Miller (Amgen); Dale Roof (Takeda); Brian Nauman (Cephalon); Joe Summers (Tap); Jim Baumann (Pfizer); Ann Gustafson (GSK); Pat Evans (BMS); Bruce Kirby (Genetech); Katheleen Carmody (Lilly); Butch Benson (Lilly); Patty Laster (Genetech). |
| **TOPIC** | **DISCUSSION** | **DECISION AND/OR ACTION** |
| I. Call to Order | • Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 10:15 a.m. | |
| II. Announcements | • Anne thanked the DUR Board for its recommendation to place Elidel® and Protopic® on Prior Authorization (PA) in May of 2005. The Package Labeling was updated in January 2006. Both drugs will carry a boxed warning about a possible cancer risk. The label also clarifies the recommendation that these drugs should be used as second-line treatments and not for children under age 2. These changes reflect the PA criteria that the Board recommended in May 2005. .<br>• Anne stated Erectile Dysfunction drugs are no longer covered by Medicaid as of January 1, 2006 per a CMS directive. | |
| III. Review and Approval of November 9, 2005 Minutes | • There were no additions or corrections to the November 9, 2005 minutes. | • Dr. Unruh made a motion to approve the minutes. The motion was seconded by Dr. Schewe. The motion carried unanimously by role call. |

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| IV. New Business<br>A. ACS Heritage | • Jason Crowe (ACS Heritage) presented two intervention proposals: Asthma Disease Management and Gastrointestinal Agents. Dr.Crowe also presented two outcomes assessments from previous intervention mailings, Falls in the Elderly and Drug Regimen Simplification. | |
| ACS Heritage<br>1. Asthma Intervention | • For Asthma Disease Management there are 4,000 potential opportunities or exceptions. The purpose of the asthma intervention is to improve treatment of asthma by identifying people with problematic therapy. In Kansas as well as other states, asthma medications account for 7.5% to 10% of utilization expenses. Some of the performance indicators include:<br>• Long acting Beta agonist as first line therapy<br>• Non-compliance which had the highest number of exceptions.<br>• Over-utilization of short-acting beta agonists will be targeted for both MDI and nebulized solutions. For nebulized solution, Dr. Crowe reviewed the excluded population.<br>• Under-utilization of inhaled steroids.<br>• Drug-drug interactions based on First Data Bank designations.<br>• Increased risk of adverse drug events.<br>• Dr. Waite questioned the indicator for nebulized levalbuterol and albuterol solutions.<br>• Dr. Crowe explained these indicators.<br>• The Board discussed changing the exception criteria for levalbuterol for the number of daily treatments from six per day to three. | • A motion was made by Dr. Waite to approve the asthma intervention with a modification to performance indicator # 2 (1) d.and e, for levalbuterol to read “4 or more treatments /day”. The motion was seconded by Dr. Grauer. The motion carried unanimously by role call. |

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| 2. Gastrointestinal Interventions | • For the Gastrointestinal Disease Management there were 15,000 potential opportunities or exceptions. Performance indicators for this intervention were discussed.<br>• Dr. Waite question high dose vs. maintenance dose over extended period of time.<br>• Anne stated there is a policy being implemented in October 2006 that should address this issue. | • A motion was made by Dr. Grauer to approve the gastrointestinal intervention. The motion was seconded by Dr. Schewe. The motion carried unanimously by role call.<br>• The Gastrointestinal letter and information will be mailed first to support the PPI policy that will be implemented in October 2006. |
| 3. Outcomes Assessment Drug Regimen Simplification | • Dr. Crowe presented the outcomes assessment for Drug Regimen simplification that was mailed in February 2005. The purpose of the assessment was to analyze prescription claims data, determine opportunities to simplify drug regimens, decrease associated costs, and to measure recipient compliance in those who were Candidates for drug regimen simplification. There were 292 adjusted targeted patients. Thirty seven (13.4%) of the patients changed to the recommended therapy with a resulting monthly savings of $2,984 and annualized savings of about $36,000. Ten (66.7%) of the noncompliant patients became compliant during the post-intervention period. | |
| 4. Falls in the Elderly | • Dr. Crowe presented the outcomes assessment for Falls in the Elderly. This intervention was mailed in June 2005.The purpose of this intervention was to reduce the risk of falls in the elderly. This was accomplished by identifying patients at the highest risk of falling, using diseases that may predispose them to falling and medications that may increase their fall risk as selection factors. There were 755 adjusted control patients. The target group tended to be older, saw more providers, and utilized more prescriptions in the baseline period than the control | • Dr. Crowe will check on the feasibility of a control group and notify Anne through e-mail of his findings.<br>• If the mailing proves to have a positive outcome, then the control group providers would be included in the intervention. |

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| 4. Falls in the Elderly (continued) | group. Each patient's individual disease-state and drug-related risk factors were combined into a single 'Falls Risk Index'. This intervention had a control group (10.3% reduction that appeared to do better than the target group (8.9% reduction). Dr. Crowe stated the control group had much smaller numbers.<br>• Dr. Burke questioned the method of selection of the control group.<br>• Dr. Crowe responded the control group contained providers that only had one patient identified for Intervention; it was based solely on the number of identified patients the provider had at the time of the assessment.<br>• Dr. Kentfield inquired about table 1: How does the average number of prescriptions differ from the average number of drugs and claims?<br>• Dr. Crowe will obtain clarification for this question and report back to the Board.<br>• Dr. Burke commented that this study suggests a decrease in opportunity of falls in the elderly, but would like to see an up-front randomized control group comparison.<br>• Dr. Crowe will evaluate the control group to see if it can be modified for future intervention outcome analysis.<br>• Dr. Burke also recommended at least one intervention with a reasonable control group be added to the study. The most compelling data would be relative to a randomized control group.<br>• Dr. Crowe is limited in the method of selecting the control group. Future interventions will focus on asthma, GI drugs, short acting opioids, and medication compliance. Dr. Crowe stated the medication compliance intervention has already been mailed. | |

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| 4. Falls in the Elderly (continued) | • Anne stated that the PPI policy would disqualify the GI mailing from having a control group.<br>• Dr. Crowe will check on the feasibility of a control group and will notify Anne through e-mails of his findings.<br>• If the mailing proves to have a positive outcome, then the control group providers would be included in the intervention.<br>• Dr. Crowe reviewed previous intervention mailings from the past two years in a brief summary. Areas of interest for future interventions for the Kansas Medical Assistance Program (KMAP) are mental health drugs and pediatrics. | |
| B. Prior Authorization Unit Report for 2005 | • Debra Quintanilla presented the 2005 Prior Authorization (PA) Unit Report. She distributed a spreadsheet showing the description of the medication, criteria origin, revision, and end dates. The spreadsheet included the number of PA's approved, denied, and cancelled with percentages. The total number of PA's for 2005 was 4,816 and the number of approved was 3,885 (81%). The denials totaled 817 (17%). The Board was complimentary of the report and felt the data suggested the PA process was working appropriately.<br>• Dr. Kentfield would like to know what dollar amount the 17% denial represents.<br>• Dr. Burke stated that details of appeal information was missing from the report and would be valuable for the board to review.<br>• Mary Lesperance explained that there are very few appeals, approximately 1 or 2 each month. Many of the appeals are resolved prior to the appeal date. Mary will check on numbers of appeals and report back on appeals.<br>• Dr. Schewe would like to see a breakdown of denials in terms of how many didn't meet criteria or. | • The Board requested the following information be reviewed at the May 2006 meeting: breakdown of denials, appeals , review the Celebrex® PA criteria, and cost savings associated with the 17% denial. |

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| B. Prior Authorization Unit Report for 2005 (continued) | didn't provide sufficient information<br><br>• Dr. Burke pointed out that the data suggests Medicaid is not being too restrictive.<br>• Kevin Waite pointed out the Regranex® criteria has a high denial rate and the criteria has not been revised in six years.<br>• The Board briefly reviewed the Regranex® criteria and felt it was still appropriate.<br>• Anne would like the board to look at criteria for those drugs with a high or low denial rate. Anne suggested reviewing the Celebrex® criteria. This will be added to the DUR agenda for May 2006. | |
| C. Rifampin<br>1. Update Prior Authorization Criteria<br>2. Public Comments (5 minutes)<br>3. DUR Board Recommendations | • Anne proposed that the Rifampin PA criteria be updated. It has been on PA since 1997 because of the price and high utilization at that time. The draft criteria will allow approval on all requests for Rifampin, except when used for tuberculosis (TB) caused by Mycobacterium tuberculosis. The treatment for this type of TB can be obtained from the Kansas Department of Health and Environment (KDHE). There were 177 requests for Rifampin last year with 4 providers during the last year referred to KDHE for TB treatment.<br>• No public comment<br>• Deb Q. explained that the PA process could be a quick phone call with no paperwork involved.<br>• Dr. Schewe suggested using ICD-9 codes at the Point of Sale (POS) and remove the PA.<br>• Karen K. recommended using an exclude edit for the TB diagnosis codes, and stated that it would need to be tested prior to implementation.<br>• Anne stated removal of PA would be appropriate, but we want to ensure all TB patients are directed to the KDHE. | • A motion was presented by Dr. Schewe to exclude theTB ICD-9 codes 010-018 at the point of sale (POS) to eliminate the PA process for Rifampin. The proposed revised PA criteria will be in place until the POS process is determined to be feasible and complete. The motion was seconded by Dr. Kentfield and approved unanimously by roll call. |

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| D. Remicade®<br>1. Update Prior Authorization Criteria<br>2. Public Comments (5 minutes)<br>3. DUR Board Recommendations | • Anne reviewed the revised draft criteria for Remicade®. It has been revised due to the recent FDA approval for the indication of ulcerative colitis.<br>• The only change to the PA criteria is the addition of the use of Remicade® for ulcerative colitis and the requirement that it be prescribed by a gastroenterologist.<br>• No public comment.<br>• Dr. Burke expressed concern about limiting the prescribing to gastroenterologists, specifically for regions in Kansas which are underserved. He suggested the medication can be ordered by a gastroenterologist first and follow-up prescriptions can be written by the Primary Care Physician (PCP) which whould alleviate his concern. | • A motion was presented by Dr. Grauer to approve the revised draft criteria. The motion was seconded by Dr. Kroeger and approved unanimously by roll call. |
| E. Amevive®<br>1. Update Prior Authorization Criteria<br>2. Public Comments (5 minutes)<br>3. DUR Board Recommendations | • The last update to these criteria was April 2004. Anne proposed the revised Amevive® Criteria with one addition (number 5) which states: 'Consumer is not HIV+ (Medication not covered for HIV+ individual) ' which reflects new information in the package labeling,<br>• No public comment.<br>• Dr. Schewe and Dr. Bryant requested adding the requirement that only a dermatologist be able to prescribe this medication. | • A motion was presented by Dr. Schewe to approve the revised draft criteria with two additions: #5 as stated on the revised draft, and the addition of #6: Must be prescribed by a dermatologist. The motion was seconded by Dr. Bryant and approved unanimously by roll call. |
| F. Orencia®<br>1. Review PA Criteria<br>2. Public Comments (5minutes)<br>3. DUR Board Recommendations | • Anne presented information about Orencia®, a new drug entity, and the proposed PA draft criteria.<br>• Public comment: Jason Beal, Bristol Meyers Squibb, stated he supported the criteria and presented information about the drug.<br>• Dr. Unruh asked about the cost of the medication.<br>• Dr. Beal stated the vials are $450 each and a patient uses approximately two to three vials per month. | • A motion was presented by Dr. Bryant to approve the proposed draft criteria for Orencia®. The motion was seconded by Dr. Waite and approved unanimously by roll call. |

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| G. Increlex®, Iplex®<br>1. Review PA Criteria<br>2. Public Comments (5 minutes)<br>3. DUR Board Recommendations | • Anne presented information on two new drugs, Increlex® and Iplex® (IGF-1 replacement therapy). Iplex® is to be released later this year and Increlex® is now on the drug file for the KMAP. These drugs are indicated for treatment of growth failure in patients with severe primary insulin-like growth factor defficiency or growth hormone gene deletion with antibodies to Growth Hormone (GH). Both of these conditions are considered very rare. It is estimated only about 6000 children in the US will meet the criteria for these medications.<br>• Anne presented the proposed PA draft criteria which is based on the package labeling of both products. Areas of concern on the proposed draft are defining normal to elevated Growth Hormone levels and measuring the standard deviations (-3SD) for IGF-1 levels. Anne indicated that Dr. Moore has been helpful in developing this proposed criteria. He suggested using 'above 25' as the cut-off for elevated growth hormone levels and submitted a recommendation for measuring the level of IGF-1 and determining a cut off.<br>• Public Comment: Dr. Moore stated that all comments are appropriate. He could only remember one or two children in the last 10 to 15 years who would fit these criteria. He stated the problem with measuring IGF-1 levels is that it is not normally distributed, so -3SD won't be feasible because the resulting number would be negative. He recommends less than the 2.5 percentile for the reference lab with age and gender adjustments. He also noted that the GH levels proposed are not restrictive enough and some people may qualify that are borderline. In his experience, the kids that would require this new medication usually have higher levels of GH. He recommends the cut off to be above 25ng/ml. He thinks we would still be able to identify all the individuals that will need to be treated.<br>• Dr. Unruh asked Dr. Moore what the expected or realized growth recovery would be for these kids with treatment.<br>• Dr. Moore stated not as good as with GH, but these kids have other consequences of IGF-1 deficiency. If treated | • A motion presented by Dr. Unruh to approve the proposed PA draft criteria for Increlex® and Iplex® with a modification to the following:<br># 3 change to "IGF-1 levels less than the 2.5 percentile for the reporting reference lab with age and gender adjustments"<br># 4 change to "Growth hormone levels greater than 25ng/ml with two stimulation tests.<br>The motion was seconded by Dr. Schewe and approved unanimously by roll call. |

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| G. Increlex®, Iplex® (continued) | early enough, they should reach their height potential.<br><br>• Dr. Burke commented that the issues with measuring IGF-1 levels to be: national standards are lacking, variability among reference labs, and a lack of normal distribution.<br>• Dr. Moore stated that there is a distribution to the left, but it just reflects the nature of IGF-1 levels; it has a large range and some of the levels were also very high. It also depends on what time of day the levels were drawn.<br>• Dr. Burke questioned if using below 2.5 % for IGF-1 levels was more inclusive than only requiring below normal levels.<br>• Dr. Moore stated if the criteria is used in combination, i.e., GH levels greater than 25ng/ml and the IGF-1 levels less than 2.5 %, you will catch everyone that needs to be treated and exclude those that could qualify with borderline GH levels.<br>• Anne asked Dr. Moore for his recommendation on the number of stimulation tests to require in determining GH levels.<br>• Dr. Moore recommends two stimulation tests. | |
| H. PDL Prior Authorization Forms Update<br>1. Review Form<br>2. Public Comment<br>3. DUR Board Recommendations | • Anne explained the changes made to the current PA form for non-preferred drugs. There has been a space added to the PA forms for prescribers to write a preferred drug prescription and fax to the pharmacy to allow dispensing of the preferred drug. | • A motion to accept the new PA Form was made by Dr. Schewe and seconded by Dr. Bryant. The form was approved unanimously by roll call. |
| V. Adjournment | | • Dr. Wilcox presented the motion to adjourn the meeting. The motion was seconded by Dr. Bryant and approved unanimously by roll call. |